

MANUFACTURING EXTENSION PARTNERSHIP

Success Stories from the Field

Puritan Products, Inc.

Manufacturers Resource Center

cGMP Compliance Paves the Way for New Markets

Client Profile:

Puritan Products, Inc., a supplier of specialty and industrial chemicals to the hypercompetitive pharmaceutical, laboratory, and semiconductor industries, specializing in contract manufacturing of custom formulations, custom solutions and dilutions, SEMI, VLSI, ACS quality chemicals, and failure analysis chemicals for decapsulation. The company utilizes in-house capability for design and construction of patented, specialized processing systems for preparation of proprietary formulations and/or custom blends for customers in the semiconductor, laboratory, pharmaceutical, and food industries. Founded in 1987, Puritan Products employs 29 people at its facility in Bethlehem, Pennsylvania.

Situation:

As a strategic initiative, Puritan Products wanted to expand its market base into the pharmaceutical, biopharmaceutical, and biotechnology industries. To sell and service these regulated industries, the company required compliance to current Good Manufacturing Practices (cGMP). To begin this marketing thrust, the company needed to identify and hire a consultant with expertise in cGMP compliance specifically with intimate knowledge of 21 CFR (Code of Federal Register) Part 211. This federal standard provided the framework for the development of a cGMP standard operating procedure (SOP) manual incorporating the specific Food and Drug Administration (FDA) compliance requirements relevant to their business. Due to its past relationship and successful project work with the Manufacturers Resource Center (MRC), a NIST MEP network affiliate, Puritan Products asked MRC to help it enter new markets that required documentation to cGMP and audits by potential buyers.

Solution:

After researching the specific cGMP requirements, MRC identified a consultant that would be a good match to generate a Standard Operating Procedure manual that is required for the new, targeted industries. The company worked with the consultant to write the manual, train their managers and train the basic workforce. As a result of the work, Puritan Products has become cGMP compliant and gained knowledge in how to match the specific market's needs with Puritan's continually expanding capabilities. Puritan Products has already entered a new market, the pharmaceutical market, by selling their USP (U.S. Pharmacopeia) grade water. The company is anxious to have its facility and quality management system audited by companies in the pharmaceutical and related industries. The cGMP protocol has opened doors to the pharmaceutical, biopharmaceutical, and biotechnology markets.

Results:

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- * Increased sales by \$150,000.
- * Invested \$86,000 in plant and workforce development.
- * Retained 4 jobs.
- * Expanded market base.

Testimonial:

"MRC is an asset that continually adds to our company's knowledge base and capabilities. We continue to utilize their expertise and that of their consultant database in identifying new growth opportunities for our company and to implement the necessary steps to ensure business growth in these areas. We trust MRC and they deliver for us time and time again."

Lou DiRenzo, President and General Manager